IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH,	:	
	:	**CIVIL ACTION**
Plaintiffs,	:	
v.	:	
	:	**NO. 22-252**
MODERNA, INC. and MODERNATX, INC.,	:	

MEMORANDUM

Goldberg, J. **November 2, 2022**

During the course of the COVID-19 pandemic, Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") brought to market an mRNA-based vaccine in an effort to combat the effect of the COVID-19 virus. Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively "Plaintiffs") claim that, in order for the vaccine to succeed, Moderna used a revolutionary lipid nanoparticule ("LNP") delivery platform—created and patented by Plaintiffs—without paying for it or requesting a license.

On February 28, 2022, Plaintiffs filed suit seeking compensation for the use of the patented technology they claim to have developed. On May 6, 2022, Moderna filed a partial Motion to Dismiss, arguing that to the extent Plaintiffs seek royalties on the sale and provision of COVID-19 Vaccine doses to the United States Government, such claims can only proceed in the Court of Federal Claims and must be dismissed from this Court. For the following reasons, I will deny Moderna's Motion.[1]

[1] On May 18, 2017, then Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this matter and other District of Delaware cases.

I. FACTUAL BACKGROUND

The following facts are taken from Plaintiff's Complaint.[2]

A. General Background Regarding Virus Vaccines

As explained in the Complaint, viruses are typically described as small packets of deoxyribonucleic acid ("DNA") or ribonucleic acid ("RNA"). If a virus enters a living host cell, the virus's DNA or RNA can hijack the cell's machinery and instruct the cell to make copies of the virus. These copies, often numbering into the millions, leave the infected cell and enter other cells where the process repeats. Infected cells can be damaged or die while hosting the virus, and, left unchecked, the host organism itself can die. Vaccines traditionally work by injecting into the body a weakened or inactive form of the virus that is unable to cause infection, but nonetheless retains features of the infectious virus and can teach the immune system to recognize and attack the infectious virus it if it invades in the future. (Id. ¶¶ 19–20.)

Moderna's COVID-19 vaccine belongs to a new class of medicines that deliver nucleic acids into the cells of the body to treat diseases or trigger an immune response to protect a person from future infection. Nucleic acids are molecules that encode the genetic information essential to sustain life. One type of nucleic acid is DNA, which is found within chromosomes and contains genetic information. In order to make the protein encoded by a particular gene, the cell first converts the genetic code in the gene's DNA into another type of nucleic acid known as messenger ribonucleic acid, or "mRNA," which is effectively a copy of the portion of DNA that the cell's protein-making machinery uses as a blueprint to assemble the protein encoded by the gene. (Id. ¶¶ 21–23.)

[2] In deciding a motion under Federal Rule of Civil Procedure, the court must accept all factual allegations in the complaint as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading, the plaintiff may be entitled to relief. See Erickson v. Pardus, 551 U.S. 89, 93–94 (2007).

Vaccines using RNA technologies are an emerging frontier in medicine to address many previously intractable diseases and new viruses. RNA-based medicines, however, have been difficult to develop because RNA molecules are fragile and, without adequate protection, are susceptible to degradation in the body. For decades, the need for an effective delivery technology had been the most significant challenge in the development of RNA-based products since, without the means to protect the mRNA, mRNA-based vaccines have been ineffective. (Id. ¶¶ 24–25.)

B. Plaintiffs' Invention

Plaintiffs allege that functional RNA-based medicines eluded researchers until the work by Plaintiffs' scientists. After years of research, Plaintiffs developed lipid nano-particle ("LNP") technology that relies on fat-like molecules called lipids to encapsulate and protect nucleic acids like mRNA from degradation in the body. Once inside, the LNP releases the nucleic acid so that it can express the protein it encodes. The lipid components of Plaintiffs' technology include structural lipids, such as phospholipids and cholesterol; "cationic" (positive charge-bearing) lipids, including "ionizable" lipids that are positive charge-bearing at certain pH levels; and conjugated lipids, which are lipids attached to a polymer such polyethyleneglycol ("PEG"). (Id. ¶¶ 26–27.)

Plaintiffs' scientists' efforts led to the first FDA-approved RNA-based therapeutic in the form of a drug called Onpattro®, used to treat a rare disease called amyloidosis. The company that developed Onpattro® did so under an LNP license from Plaintiffs. Building on this initial success, Plaintiffs have granted licenses for its LNP technology to other companies. From 2011 to 2021, the United States Patent and Trademark Office ("PTO") issued to Plaintiffs six different patents for its LNP-based inventions. (Id. ¶ 28–29.)

C. The Alleged Infringement and Related Litigation

According to the Complaint, Moderna has been on actual notice of Plaintiffs' patents before development of its COVID-19 vaccine, the "Accused Product" in this matter. Indeed, in May 2015, Moderna attempted to acquire rights to Plaintiffs' LNP delivery technology for four specific viral targets

through sublicense from a Canadian company called Acuitas Therapeutics ("Acuitas"). Although Acuitas had licensed the LNP technology in 2012, its license agreement limited its ability to grant sublicenses. Nonetheless, Acuitas granted Moderna the sublicense. In August 2016, after learning of the sublicense agreements, Plaintiffs notified Acuitas of material breach, and Acuitas filed suit in the Supreme Court of British Columbia seeking to prevent Plaintiffs from terminating the license. In February 2018, Plaintiffs and Acuitas settled their dispute and agreed that Acuitas could no longer use the LNP technology except for the specific sublicenses given to Moderna for vaccines targeting specific viruses remaining in effect. SARS-CoV-2, the virus that causes COVID-19, was not among the surviving sublicenses. (Id. ¶¶ 31–34.)

Moderna then began filing *inter partes* review ("IPR") petitions, requesting that the PTO cancel certain of Plaintiffs' patents, including some asserted here. Although the first IPR petition was successful, the remaining IPR petitions were not. (Id. ¶¶ 35–38.)

On January 10, 2020, with the novel SARS-CoV-2 virus quickly spreading around the world, scientists identified the virus's complete genetic sequence and posted it for free on the internet, thus revealing the complete RNA sequence that encodes the virus's components, including its distinctive "spike protein." With that information in the public domain, researchers around the world, including Moderna, begin designing vaccines to target the virus. (Id. ¶ 39.)

Relying on Plaintiffs' LNP technology covered by the Asserted Patents, Moderna was able to begin producing its COVID-19 vaccine within just a few days of the genomic sequence entering the public domain. Moderna's success was unprecedented. On February 24, 2020, Moderna shipped clinical drug product, and, less than one month later, Phase I trials began. Plaintiffs contend that Moderna's COVID-19 vaccine could not have been developed on such a short timeline without Plaintiffs' proven and patented LNP delivery technology. Plaintiffs further allege that published articles and statements released by Moderna explicitly showed Moderna's use of Plaintiff's patents. (Id. ¶¶ 41–49.)

Moderna's distribution of its Accused Product and its administration to persons in the United States and worldwide commenced around December 18, 2020, immediately after the FDA granted Moderna's COVID-19 vaccine an Emergency Use Authorization ("EUA"). In 2021, Moderna shipped 807 million doses, and, as of February 2022, Moderna had signed advance purchase agreements worth approximately $19 billion for all of 2022. The Complaint alleges that the vaccine doses made and administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individual vaccine recipients in the United States. (Id. ¶ 51.)

On June 1, 2021, Moderna announced that it had initiated the FDA process for a Biologics License Application ("BLA")—full-fledged licensure of its COVID-19 vaccine. The FDA approved the BLA on January 31, 2022. As of February 24, 2022, the vaccine had received at least emergency authorization from more than seventy countries. Moderna has contracted with a number of companies around the world to manufacture its COVID-19 vaccine, including companies that employ facilities in the United States. (Id. ¶¶ 52–54.)

Plaintiffs claim that they did not seek to inhibit development and distribution of the vaccine but only requested fair and reasonable compensation. As such, they proposed that Moderna pay for a mutually acceptable license, but Moderna has declined to engage meaningfully in licensing discussion, necessitating this lawsuit. (Id. ¶¶ 55–61.)

On February 28, 2022, Plaintiffs filed suit alleging infringement of six different patents, prompting Modern to file the partial motion to dismiss currently pending before me. [3]

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see

[3] The Complaint seeks damages for all sales of the COVID-19 Vaccine within the United States. Moderna's Motion to Dismiss addresses only those sales that were made to the United States Government and does not seek dismissal of claims relating to any other sales.

also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). The United States Supreme Court has recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quotations omitted). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" and "only a complaint that states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id.

The United States Court of Appeals for the Third Circuit has detailed a three-step process to determine whether a complaint meets the pleadings standard.[4] Bistrian v. Levi, 696 F.3d 352 (3d Cir. 2014). First, the court outlines the elements a plaintiff must plead to state a claim for relief. Id. at 365. Next, the court must "peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth." Id. Finally, the court "look[s] for well-pled factual allegations, assume[s] their veracity, and then 'determine[s] whether they plausibly give rise to an entitlement to relief.'" Id. (quoting Iqbal, 556 U.S. at 679). The last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. (quoting Iqbal, 556 U.S. at 679).

III. DISCUSSION

Moderna contends that it contracted with the Government for production and delivery of the vaccine for use in combatting the pandemic. It presses that, under 28 U.S.C. § 1498(a), any infringement claims relating to a Government contract must be litigated exclusively in the Court of Federal Claims.

[4] The Federal Circuit applies the law of the circuit in which the district court sits to nonpatent issues such as the standard for motions to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). In re TLI Commc'ns LLC Patent Litig., 823 F.3d 607, 610 (Fed. Cir. 2016).

Accordingly, Moderna seeks dismissal, under Federal Rule of Civil Procedure 12(b)(6),[5] of any of Plaintiffs' infringement claims premised on Moderna's sale and provision of COVID-19 vaccine doses to the United States Government.

28 U.S.C § 1498(a) provides:

> Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. Reasonable and entire compensation shall include the owner's reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity that had no more than 500 employees at any time during the 5-year period preceding the use or manufacture of the patented invention by or for the United States. Not[]withstanding the preceding sentences, unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust.
>
> For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm or corporation for the Government and with the authorization of the consent of the Government, shall be construed as use or manufacture for the United States.

Id. at § 1498(a).

The "intention and purpose of Congress" in enacting this statute was "to stimulate contractors to furnish what was needed" by the government, "without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents." Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 345 (1928). "Th[is] provision provides a cause of action against the United

[5] Since section 1498(a) is an affirmative defense rather than a jurisdictional bar, a court may not dismiss such an action under Federal Rule of Civil Procedure 12(b)(1). Toxgon Corp. v. BNFL, Inc., 312 F.3d 1379, 1382 (Fed. Cir. 2002).

States (waiving sovereign immunity) for a patent owner to recover damages for the unauthorized use or manufacture of a patented invention '*by or for* the United States." Astornet Techs. Inc. v. BAE Sys., Inc., 802 F.3d 1271, 1277 (Fed. Cir. 2015) (internal quotations omitted) (emphasis in original). Section 1498 "creates an independent cause of action for direct infringement by the Government or its contractors that is not dependent on 35 U.S.C. § 271(a)." Zoltek Corp. v. United States, 672 F.3d 1309, 1326–27 (Fed. Cir. 2012). For claims that fall within the statute's ambit, the remedy against the United States is exclusive. Astornet, 802 F.3d at 1277.[6]

Section 1498(a) establishes an affirmative defense, not a jurisdictional bar. Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 554 (Fed. Cir. 1990). A section 1498 affirmative defense is a highly factual determination. Saint-Gobain Ceramics & Plastics, Inc. v. II-VI, Inc., 369 F. Supp. 3d 963, 970 (C.D. Cal. 2019). A defendant bears the burden of establishing that "(1) the [infring]ing use is 'for the Government' and (2) the [infringing] use is 'with the authorization and consent of the Government.'" Sevenson Envt'l Servs., Inc. v. Shaw Envt'l, Inc., 477 F.3d 1361, 1365 (Fed. Cir. 2007).

A. "For the Government"

The first part of the test under § 1498 is whether the infringing use was "for the Government." "A use is 'for the Government' if it is 'in furtherance and fulfillment of a stated Government policy' which serves the Government's interests and which is 'for the Government's benefit.'" BAE Sys. Info. & Elec. Sys. Integration Inc. v. Aeroflex Inc., No. 09-cv-769, 2011 WL 3474344, at *9 (D. Del. Aug. 2, 2011) (quoting Madey v. Duke Univ., 413 F. Supp. 2d 601, 607 (M.D.N.C. 2006)). The Federal Circuit has remarked that this prong is satisfied where "the use or manufacture of a patented method or apparatus occur[s] pursuant to a contract with the government and for the benefit of the government." Sevenson, 477 F.3d at 1365. The Government's benefit need not be the "primary purpose" of a government contract. Id. at 1365. Likewise, the Government need not be the sole beneficiary. IRIS Corp. v. Japan

[6] Federal Circuit law applies to issues of substantive patent law. In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 803 (Fed. Cir. 2000).

Airlines Corp., 769 F.3d 1359, 1362 (Fed. Cir. 2014) (quoting Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371, 1378 (Fed. Cir. 2009)). This provision must be applied on a "case-by-case basis to determine whether a use meets the articulated statutory requirements." Madey, 413 F. Supp. 2d at 607.

Nonetheless, "[i]ncidental benefit to the government is insufficient." IRIS Corp. v. Japan Airlines Corp., 769 F.3d 1359, 1361 (Fed. Cir. 2014). Moreover, a governmental grant of authorization or consent, standing alone, does not mean that the alleged use or manufacture is done "for the United States" under § 1498(a). Id. at 1362. "Even where 'the government has an interest in the program generally, or funds or reimburses all or part of [that program's] costs,' the Government's interest is too remote 'to make the government the program's beneficiary for the purposes underlying § 1498.'" Sheridan v. United States, 120 Fed. Cl. 127, 131 (Fed. Cl. 2015) (quoting Larson v. United States, 26 Cl. Ct. 365, 369 (1992)).

Here, Moderna alleges that, under its contract with the United States Government, its supply of the COVID-19 vaccine is for the benefit of the Government and thus § 1498(a) is applicable. Moderna reasons that, in August 2020, the Government used its emergency powers to contract with Moderna to supply doses of the COVID-19 vaccine. (Def.'s Ex. A.)[7] The Contract notes that the novel coronavirus had spread globally resulting in an outbreak in the United States, which constituted a national emergency. (Id. § C.1.1.) The Contract further provides that, "[t]he Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national

[7] The Contract is a public document published on the internet at https://www.hhs.gov/sites/Default/files/moderna-covid-19-vaccine-contract.pdf. Federal Rule of Evidence 201(b) permits a district court to take judicial notice of facts that are "not subject to reasonable dispute" in that they are either (1) "generally known within the territorial jurisdiction of the trial court" or (2) "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Courts regularly take notice of similar documents, particularly federal government or federal agency documents published on websites or otherwise. See U.S. ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 140 (E.D. Pa. Dec. 20, 2012) (citing cases).

emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population." (Id. § C.1.) Specifically, the Contract states:

> Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

(Id. § C.1.1.1.)

Moderna contends that this contract language unequivocally demonstrates that its production of the COVID-19 vaccine was "for the Government." It claims that it supplied, and continues to supply, COVID-19 vaccine doses to the U.S. Government for the Government to achieve a specific government objective, *i.e.*, supporting a nationwide vaccination effort.

Plaintiffs respond that for the infringing acts to be "for the Government," the Government benefit must be direct and not merely incidental. Thus, when the Government authorizes third-party action, it is not liable for any infringement caused by the third party, but rather only for the infringement actually done for the U.S. Government. Under this standard, Plaintiffs claim that Moderna cannot meet its burden at the pleading stage to show that the government-funded sales of the vaccine were "for the Government." Plaintiff presses that the Complaint alleges that the infringing acts were not for the *Government's* benefit, but rather for the benefit of individual vaccine recipients in the United States, *i.e.*, the American people. (See Compl. ¶ 51 ("Moderna's vaccine doses made in the United States and administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other

entities for the benefit of individual vaccine recipients in the United States. All of the manufacturing and sales of vaccines distributed in the United States were for the benefit of the American public.").) According to Plaintiffs, the Contract between Moderna and the Government is not contrary as it merely emphasizes the importance of the goal in finding an effective COVID-19 vaccine.

In Advanced Software Design Co. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371 (Fed. Cir. 2009), the Federal Circuit considered what constituted a use "for the government." There, the United States Treasury required privately owned and operated Federal Reserve Banks to use a certain "seal encoding" system to identify fraudulent bank checks. Id. at 1373. Subsequently, the plaintiff sued three Federal Reserve Banks and the company that supplied their fraud detection technologies, alleging that the use of the mandatory seal encoding system constituted infringement of its patented methods. Id. The Federal Circuit found that the Government benefitted from averting fraud in Treasury checks and in saving Treasury resources through more efficient technology. Id. at 1378. Affirming the district court's grant of judgment for the plaintiff, the court noted that "the benefits to the government of using the seal encoding technology on Treasury checks are not incidental effects of private interests." Id. at 1379.

Similarly, in Saint-Gobain Ceramics & Plastics, Inc. v. II-VII Inc., 369 F. Supp. 3d 963 (C.D. Cal. 2019), the plaintiff filed an infringement suit against defendants based on defendants' manufacturing and sale of single crystal sapphire sheets used in the manufacture of windows for aircrafts. Following discovery, defendants moved for summary judgment raising a defense under § 1498. Id. at 966–67. In granting summary judgment, the United States District Court for the Central District of California found that defendants' research and development of the sapphire sheets was "for the government" in order to fulfill the window panel contracts defendants had executed with government contractor, Lockheed Martin, and that defendants sold their sapphire sheets exclusively to the United States Government through Lockheed Martin. Id. at 980. Although the court recognized that defendants

stood to benefit financially from developing the capability to grow sapphire sheets, it noted that, for § 1498(a) to be triggered, the United States did not need to be the sole beneficiary. Id.

By contrast, the United States Claims Court[8] reached the opposite conclusion in Larson v. United States, 26 Cl. Ct. 365 (Cl. Ct. 1992). There, the plaintiffs were the owner of patents for splints used in treating patients for broken bones, strains, arthritis, and burn injuries, as well as for application of the split to the patient under certain specified conditions. Id. at 367. Health care providers participating in the government programs of Medicare, Medicaid, and the Civilian Health and Medical Program for the Uniformed Services used the plaintiff's splints in medical treatment, the costs of which were reimbursed by the government programs. Id. The plaintiffs argued that the language of the Medicare Act supported the assertion that the infringing activity was "for" the benefit of the government because the government has an interest in providing treatment to certain segments of the population and it received a benefit from services reimbursed under Medicare. Id. at 369. The Claims Court disagreed, finding that "[m]edical care is provided for the benefit of the patient, not the government." Id. It reasoned that "[a]ny use of plaintiffs' casts and splints was for the benefit and convenience of the patient and provider, with no benefit to the government. The fact that the government has an interest in the program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program's beneficiary for the purposes underlying § 1498." Id.

At this early stage of the litigation, I find this case more akin to Larson than Advanced Software Design or Saint-Gobain Ceramics. Based on the allegations of the Complaint, which I must accept as true, the development and sale of the vaccines was for the benefit of the vaccine's recipients. According to the Complaint, the U.S. Government was an incidental beneficiary who bore an interest in ensuring the safety of its citizens. As Plaintiffs convincingly note, to credit Moderna's argument based on the

[8] In the Court of Federal Claims Technical and Procedural Improvements Act of 1992, the statute substituted the "Court of Federal Claims for the "Claims Court." See Keene Corp. v. United States, 508 U.S. 200, 206 n.2 (1993).

preamble language of the contract—a contract produced here only in redacted form—could mean that every government-funded product used to advance any policy goal articulated by the U.S. Government-—such as IV needles to fight HIV to cancer drugs to fight the war on cancer—would be subject to a § 1498(a) defense. This is particularly true in this case where the race to develop a COVID-19 vaccine may have occurred even in the absence of Government involvement and was simply expedited by the national effort to hasten the process.

Absent clear language, either in the Complaint or the Contract, establishing that the development of the vaccine was "for the Government," I find that this dispute is not appropriate for resolution in a Rule 12(b)(6) motion. As noted above, section 1498(a) is an affirmative defense rather than a jurisdictional bar. Toxgon Corp. v. BNFL, Inc., 312 F.3d 1379 (Fed. Cir. 2002). Accordingly, the moving party bears the burden of proving that defense, and, if appropriate, a § 1498(a) dispute should be resolved by summary judgment rather than on a motion to dismiss. Id. at 1382–83. Consistent with this principle, every case cited by the parties on this issue resolved the matter on a motion for summary judgment, after the parties had taken discovery, and not on motions to dismiss.[9] Such an issue cannot be resolved without some inquiry into the full and complete terms of the contract regarding

[9] In its reply brief, Moderna cites cases wherein the court granted Rule 12(b)(6) motions to dismiss claims under § 1498(a). These cases do not undermine the general principle that an analysis under § 1498(a) is a highly factual inquiry that *generally* should not be resolved on a motion to dismiss. Nor do these cases detract from the fact that the vast majority of § 1498(a) arguments are resolved on summary judgment motions.

Indeed, upon review, the cases cited by Moderna are aligned with these precepts. In IRIS Corp. v. Japan Airlines Corp., 769 F.3d 1359, 1363 (Fed. Cir. 2014), the district court placed heavy reliance on the facts that (a) the contract at issue involved a "uniquely governmental function" and (b) the Government had "unequivocally stated its position that suit under § 1498(a) is appropriate." Id. at 1363. In D3D Technologies, Inc. v. Microsoft Corp., No. 20-cv-1699, 2021 WL 2194601, at *1 (M.D. Fla. Mar. 22, 2021), the district court, in a truncated analysis, observed that the complaint explicitly conceded that the alleged infringing technology was developed pursuant to a contract with the United States Army to supply the Army with augmented reality technology. Id. at *2. Finally, in Astornet Technologies Inc. v. BAE Systems, Inc., 802 F.3d 1271, 1277–78 (Fed. Cir. 2015), the complaint alleged no claims of direct infringement against the defendant, but rather pled only indirect infringement based solely on the Government's use—through the Transportation Security Administration—of the alleged infringing technology. Accordingly, there was no factual dispute that the alleged infringement was "for the Government." Id.

compensation for the vaccine, the parties' negotiations, and the parties' understandings as to the precise beneficiaries. While discovery may reveal that all, some, or none of the alleged infringing activity was "for the Government," the limited record appropriate for consideration at this stage does not allow me to make any such determination.

B. With the "Authorization and Consent" of the Government

I also decline to find that Moderna has unequivocally met its Rule 12(b)(6) burden of establishing that the alleged infringement was with the "authorization and consent" of the Government. Under § 1498, the "authorization and consent" of the government may be express or implied. Golden v. United States, 137 Fed. Cl. 155, 175 (Fed. Cl. 2018); TVI Energy Corp v. Blane, 806 F.2d 1057, 1060 (Fed. Cir. 1986). "When the Government provides express consent, that consent may be very broad, extending to any patented invention and any infringing use, or may be limited to only certain patented inventions or to only those uses that are necessary or are specifically consented to by the Government." Madey, 413 F. Supp. 2d at 608. "Where . . . a government contract contains an explicit authorization and consent clause (and the parties have alleged no alternative source for government authorization and consent), the scope of the government's authorization and consent to liability naturally hinges on the language of that clause." Sevenson, 477 F.3d at 1366–67. "For example, the government may give its authorization or consent to patent infringement by including in a contract 'instructions, . . . specifications[,] or drawings which impliedly sanction and necessitate infringement.'" Power Density Solutions LLC v. United States, 159 Fed. Cl. 208, 214 (Fed. Cl. 2022) (quoting Hughes Aircraft Co. v. United States, 534 F.2d 889. 901 (Ct. Cl. 1976)).

An implied authorization to infringe may be found where: "(1) the government expressly contracted for work to meet certain specifications; (2) the specifications cannot be met without infringing on a patent; and (3) the government had some knowledge of the infringement." Larson, 26 Cl. Ct. at 370. "Even when the government expressly consents to infringement in order to perform a government contract, a government contractor's use of a patented device d[oes] not constitute authorization or

consent where the choice of the device was the contractor's and where there was nothing in the contract that could not be performed without using the device." Id. at 370–71 (citing Carrier Corp. v. U.S., 534 F.2d 678, 247–48 (Ct. Cl. 1976)). "Implied government consent to infringement has been found only where particular government specifications required a particular patent infringement." Windsurfing Int'l, Inc. v. Ostermann, 534 F. Supp. 581, 588 (S.D.N.Y. 1982).

Here, Moderna argues that the Government explicitly authorized and consented to Moderna's manufacture and sale of the COVID-19 vaccine. The contract incorporates by reference Federal Acquisition Regulation 48 C.F.R. § 52.227-1(a) (2020), which states that "[t]he Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent—(1) [e]mbodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract . . ." Id. Moderna presses that because the LNPs covered by Plaintiffs' patents are part of and embodied in the "structure or composition" of the COVID-19 vaccine covered by the contract, the Government has given its authorization and consent to the alleged infringement.

Although the incorporation of FAR 52.227-1 in contracts has been deemed to constitute "authorization and consent," see Saint-Gobain Ceramics & Plastics, Inc. v. II-VII Inc., 369 F. Supp. 3d 963, 980 (C.D. Cal. 2019), even express authorization and consent may be limited by other clauses in a contract. Golden v. United States, 137 Fed. Cl. 155, 172 (Fed. Cl. Ct. 2018). The contract before me here is incomplete and heavily redacted. While Moderna posits that all of the relevant portions of the contract are available, any ruling as to authorization and consent would be premature given that it remains unsettled whether the Government, in seeking to hasten the development of a vaccine, actually consented to the use of a patented invention and agreed to accept any liability for such use. Moreover, unlike many of the cases in which the courts find authorization and consent based on the inclusion of FAR 52.227-1 in the contract, the Government has not filed any statement of interest indicating its express consent to the accused activities. See, e.g., Arlton v. Aerovironment, Inc., No. 20-cv-7438, 2021

WL 1589302, at *9 (C.D. Cal. Apr. 22, 2021) (finding "authorization and consent" prong met where Government filed a statement of interest in the case providing express consent to the accused activities). Given that "authorization and consent" prong is best considered under a more fully developed record, I decline to resolve this issue here.

Accordingly, Moderna's Motion to Dismiss will be denied. An appropriate Order follows.